

Remarks

Claims 1-46 are pending. Applicants now affirms the previous telephonic election of 4 April 2006 of claims 1-16 and 32-46. Claims 17-31 are therefore withdrawn from consideration; Applicants reserve the right to prosecute these withdrawn claims in a continuing patent application. Claims 1-16 are rejected as allegedly obvious in view of certain alleged prior art references. Claims 32-46 are rejected as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Still further, Applicants' claims and specification have been objected to as containing several spelling and grammatical errors. The specification and claims 1-16 & 32-46 are currently amended. Applicants now add new claim 47. No new matter has been added. Applicants respectfully traverse the rejections and objections, and request reconsideration and allowance of the pending claims.

Claim Rejections based on §§ 101 and 112

Claims 32-46 are rejected as failing to particularly point out and distinctly claim the subject matter of the invention, and further for failing to be proper process claims. Applicant has now amended these claims to comply with §§ 101 and 112. Applicants respectfully request reconsideration and withdrawal of the rejections.

Claim Rejections based on § 103

Claims 1-16 are rejected as allegedly obvious in view of the combination of Farooqi (U.S. Patent No. 6,254,926), Lawlor (U.S. Patent Publication No. 2003/0103914) and Thiebaud (FR 2,2509,609). Claims 13-15 are rejected as obvious in view of the previously mentioned references in further combination with Melman (U.S. Patent Publication No. 2002/0156130).

The Examiner contends that the Farooqi patent teaches a dental composition comprising *Zanthoxylu armatum*, while the Lawlor reference allegedly teaches oral compositions having citrus. The Examiner further contends that Thiebaud teaches oral compositions comprising carbon black and Melman teaches using acetic acid. The Office Action views Applicants' present invention as "obvious to try" in view of the cited references. Rendering an invention obvious to try, however, is insufficient to establish a case of *prima facie* obviousness. *See In re*

O'Farrell, 853 F.2d 894 at 903 (Fed. Cir. 1988). In view of the arguments presented herein, Applicants respectfully traverse the rejections and objections, and request reconsideration and allowance of the pending claims.

The Examiner correctly notes that the Farooqi reference does not disclose using *Zanthoxylu armatum* in combination with *Citrus karna*, *Azadirachta indica*, nor *Oriza sativa*. See 19 April 2006 Office Action at p.8. Nor does the Lawlor reference disclose the use of citrus extract with *Zanthoxylu armatum*, *Azadirachta indica*, or *Oriza sativa*. See 19 April 2006 Office Action at p. 9. The Examiner's references, including Thiebaud and Melman, lack any teaching or motivation to combine its constitutes with those features of Applicants' claims. It is improper for the Examiner merely to focus on the differences between the alleged prior art and the claimed invention, and then to state that such individual differences are obvious; the question is whether the claimed invention as a whole, rather than the differences, would have been obvious. See *Stratoflex, Inc. v. Aeroquip Corp.*, 218 USPQ 871 (Fed. Cir. 1983)

Applicants contend that the Examiner has engaged in impermissible hindsight reconstruction and has used Applicant's own specification as a blueprint to cobble together references which arguably bear on Applicants' claims. The Examiner "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the invention." See *In re Fine*, 5 USPQ.2d 1596, 1600 (Fed. Cir. 1988). Still further, the mere fact that the references may be modified in the manner suggested by the Examiner does not make such modifications obvious. See *In re Zurko*, 42 USPQ.2d 1476 (Fed. Cir. 1997). At best, the Examiner's references present a mere "invitation to explore" various combinations or additives but such an invitation does not obviate Applicants' pending claims. See *Ex parte Obukowicz*, 27 USPQ.2d 1063 (BPAI 1992).

For example, Farooqi discloses that *Azadirachta indica* is a common chewing stick and useful for its antiseptic and astringent action. See Farooqi, at col. 3. The reference goes on, however, to explain that such traditional sources suffer from a number of disadvantages and proposes its formulation to be superior to those compositions previously known. See Farooqi at col. 4 and 5. Farooqi does not teach, disclose, or even suggest the desirability of combining *Azadirachta indica* with anything at all, including the various features of Applicants' claims. Indeed, Farooqi goes on to include *Zingiber officinale* and *Quercus infectoria*, rather than

Azadirachta indica, as the respective antiseptic and astringent components of its dental composition. *See Id.* at col. 8, lines 20-30. Farooqi also arguably discloses rice husk as a constituent of conventional tooth powders, but goes further to term these compositions as not effective and even harmful for gums and teeth. *See Farooqi* at col. 4, lines 25-29. The Farooqi reference further fails to disclose, teach or even suggest the use of *Citrus karna*. Applicant respectfully reminds the Examiner that the references, themselves, must suggest the desirability or obviousness of making the combination without the slightest recourse to the teachings of Applicants' disclosure. *See In re Dance*, 48 USPQ.2d 1635, 1637 (Fed. Cir. 1998). Without such independent suggestion, the prior art is to be considered merely to be inviting unguided and speculative experimentation which is not the standard with which obviousness is determined. *See In re Laskowski*, 10 USPQ.2d 1397, 1398 (Fed. Cir. 1989).

And while the Lawlor reference discloses the citrus plant family, the reference fails to specifically mention *citrus karna* or any of the other elements of Applicants' claim 1. Here, the general disclosure of the citrus family does not obviate Applicant's recitation of *Citrus karna*. Indeed, a reference that broadly discloses a genus does not necessarily describe the various species of the genus. *See* MPEP § 2112; *also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) ("[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.) (emphasis added); *also In re Kaplan*, 229 USPQ 278,681 (Fed. Cir. 1986) (generic claims in application are patentably distinct from patented species claims). Here, Lawlor discloses over 10 species of citrus plant, but fails to specifically mention *Citrus karna*. The Lawlor reference further lacks any teaching, or suggestion, that *Citrus karna* is equivalent to the recited citrus species. The Lawlor reference goes to great lengths to explain the surprising and unexpected synergistic results of its citrus components in combination with oral care actives such as polyphosphates, phyrophates, potassium nitrate, metal salts, etc. *See Lawlor* at paras. 0011-0015 and 0053-0070. There is simply no disclosure, teaching, or even suggestion that *Citrus karna* would, in fact, result in such surprising and synergistic effects when combined with Lawlor's recited oral care actives. Even assuming, *in arguendo*, that Lawlor's written description encompassed *Citrus karna*, there is still

no disclosure, teaching or suggestion that such surprising and unexpected synergistic results would occur when *Citrus karna* is combined with *Zanthoxylu armatum*, *Azadirachta indica*, or *Oriza sativa*. There is nothing in the reference which would lead one of ordinary skill to combine *Citrus karna* with anything but the disclosed oral care actives. Hence, there is no motivation to modify or combine Lawlor to arrive at the invention disclosed by Applicants' pending claims. See MPEP 2143.01; also *In re Kotzab*, 55 USPQ2d 1313 (Fed. Cir. 2000) (mere fact that modification to prior art was allegedly within capabilities of one skilled in art was not sufficient to maintain an obviousness rejection); also *In re Dow Chemical Co.*, 5 USPQ.2d 2529, 1532 (Fed. Cir. 1989) (a suggestion for endless combination or experimentation is not a case of *prima facie* obviousness).

Indeed, in formulating, the Examiner's statements and proposed modifications improperly change the basic principle of operation of the Lawlor reference. See MPEP 2143.01; also *In re Ratti*, 123 USPQ 349 (CCPA 1959). Such modifications to make the teachings of the cited reference fit Applicants' invention are not permitted. Simply put, Lawlor does not disclose, teach or even suggest the specific use of *Citrus karna*, nor does the reference provide any motivation to combine *Citrus karna* with *Zanthoxylu armatum*, *Azadirachta indica*, or *Oriza sativa*.

The Examiner's reliance on Theibaud is also error. The Examiner correctly notes that Theibaud's carbon black was not obtained from *Oriza sativa* (as required by Applicant's claims). See 19 April 2006 Office Action p. 9. The Examiner goes on to state that "carbon black is the same no matter the source." *Id.* Thus, the Examiner has not satisfied his burden of proving the existence of Applicant's recited claim elements in the prior art. According to the MPEP, the fact that a certain characteristic may be present is *not sufficient to establish the existence of that characteristic*. The Examiner "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference...[it] may not be established by probabilities or possibilities." *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). Here, the Examiner has improperly ignored an express requirement of Applicants' claims, and later supports this position by relying on apparent personal knowledge. Applicants respectfully invite the Examiner to provide an affidavit as to the uniformity and commonality of carbon black, and the equivalence to carbon black obtained from *Oriza sativa* charred husk. Lacking

such an affidavit, the Theibaud reference fails to provide each and every limitation of Applicants' claims. *See In re Royka*, 180 USPQ 580 (CCPA 1974) (all words in a claim must be considered in judging the patentability of that claim against the prior art).

In sum, the cited references, singly and in combination, fail to provide a *prima facie* case of obviousness. Applicant therefore contends that independent claims 1 and 32 (and their respective dependant claims) are nonobvious.¹ For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the § 103 rejections.

Conclusion

It is respectfully submitted that all pending claims are in condition for allowance, and Applicants respectfully request that allowance be granted at the earliest date possible. Should the Examiner have any questions or comments regarding Applicants' response, the Examiner is asked to contact Applicants' undersigned representative.

¹ Therefore, the Examiner's rejections of dependant claims 13-15 based on Melman are deemed moot.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573.

Respectfully submitted

PALPU PUSHPANGADAN et al.

BY 

DANIEL A. MONACO
Registration No. 30,480
DRINKER BIDDLE & REATH LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
(215) 988-3312 - Phone
(215) 988-2757 – Fax
Attorney for the Applicants

**HERBAL ORO-DENTAL CARE COMPOSITION AND PROCESS FOR
PREPARING THE SAME****FIELD OF INVENTION**

5 The present invention relates to synergistic ~~Herbal~~herbal oro-dental care
10 composition used for preventing dental problems and a process for preparing the
same. More particularly, the composition comprises herbs such as *Citrus karna*,
Zanthoxylum armatum, *Azadirachta indica* and *Oriza sativa*.

BACKGROUND AND PRIOR ART

15 Bacterial aggregation on the teeth is known as plaque and causes dental caries,
gingivitis, periodontitis and other gum diseases. A variety of microorganisms are
present in the oral cavity. These range from the natural flora of the host to pathogenic
species. Among these microorganisms are the gram-positive rods associated with the
20 formation of plaque (a dense, enamel-adherent, microorganism-containing
polysaccharide matrix). Specific areas, including periodontal and sub gingival spaces
and interpapillary spaces of the tongue present environments that harbor bacteria.
These spaces are difficult to reach by tooth brushing, and are only moderately affected
by standard mouthwashes. Mechanical methods have been used for some time for the
25 prevention of dental plaque but have not generally achieved sufficient results. Studies
have shown that mechanical methods, such as the use of dental floss and inter-space
brushes do not efficiently eliminate plaque. The persistence of these microorganisms
in such environments greatly increases the risk of calculus and plaque build up and
carrier formation, which in turn presents the danger of gingival inflammation and
30 periodontal disease. Thus, chemical plaque control as a substitute or supplement to
mechanical methods is sought. *Azadirachta indica* is useful for anti bacterial/
antiprotozoal activity and eliminating plaque from the tooth.

The essential oil obtained from the peel off of *Citrus karna* is useful for
discoloration of teeth or tongue, desquamation and soreness of oral mucosa, ~~it is not~~
35 ~~having~~while avoiding objectionable taste, toxicity and imbalance of the oral flora.
Whereas chemicals like chlorhexidine ~~is known~~are known to stain teeth, and has been
know to cause tissue necrosis of the tongue and gums which may persist in tissue.
~~Also,~~The chemically also generally have poor cleansing qualities. Hydrogen peroxide

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 has poor antibacterial properties, but works very well by using bursts of oxygen to flush out debris and cleanse the oral cavity.

The Botanical descriptions of various plants which are known ~~to~~for use in various dental problems ~~are~~include:

~~Oryza~~Oryza *sativa*

Family: Poaceae

- 10 **Botanical description:** Rice is one of the oldest of food crops and has been in cultivation in India, China, Java and East Africa from very ancient time. Carbonized paddy grains and husks have been found in the excavations at Hastinapur (Uttar Pradesh) dated 1,000 –800 B.C. It is an annual or perennial grass without a rhizome; leaves long and narrow, 30-50cm.X 1.2-2.5 cm., slightly pubescent with spiny hairs
 15 on the margin.

Citrus karna Raf.

Family: Rutaceae

- Botanical description:** Medium trees 3-9 m tall, branches spreading spinous, spines long, sharp up to 5 cm long; Lvs. unifoliolate, petiole 1.0-1.5 cm long, marginate to very narrowly winged, lamina 9.0-10.5 x 5.5-6.0 cm, elliptic-oblong or elliptic-ovate,
 20 base rounded, apex subacute / retuse, margins serrulate, coriaceous, green, flowers axillary, solitary, or in 3 or 4 nate cymes, pedicels green, short *ca* 5 mm long, calyx copular 5 mm long, 7 mm broad, greenish-white with purplish tinged dorsally, 20 mm long 6 mm broad, base truncate, apex obtuse, imbricate in ~~bubs~~bulbs, wide opening, narrowly oblong, slightly asymmetric above; Flowers male and bisexual, stamens
 25 about 25, irregularly polyadlphous, filament short and long, white; anthers yellowish, disc greenish, annular, lobed, pistillodes minute, ovary green, 5 mm long, oblong; style greenish-white, 1 cm long; stigma capitate, 3-4 mm long; Disc green, annular; Fruits solitary or 3-4 in end of branchlets, fruiting pedicels short, attachment not strong, 9-12 x 8-10 cm base concave, apex sharply mammilate, mammae flat to broad,
 30 shape subglobose to subobovoid, epicarp orange-yellowish, thick, bumpy, warty, glandular (pitted) about 1 mm thick, glands dimorphic in cross section, mesocarp white, spongy, up to 2 cm thick, sweetish endocarp 8 or 9 segments, attachment strong, flesh orange-yellowish, juice sour, aromatic, central axis solid to semi hollow, white, juice glands slender, tapering; Seeds 10-12mm long, 4-6 mm broad, ovoid –
 35 oblong, seed coat creamy white, streaked, inner coat grey-brownish, cotyledon white, chalazal spot reddish, polyembryonic.

5 ***Azadirachta indica* A. Juss.** Family: Meliaceae

Botanical description: Commonly called as-Neem, abundantly found in Indian sub-continent. It is a large sized evergreen tree, with alternate, exstipulate green coloured bitter leaves, new leaves may appear in March-April.

Phytochemistry: Siddiqui (1942) isolated crystalline bitter compound nimbidin,
10 Butterworth and Morgan (1968) isolated azadiractin in crystalline form.

Medicinal use: *Azadirachta indica*, a plant used widely in Ayurveda, has been reported to have anti-inflammatory, immunomodulatory and adaptogenic properties. The present study evaluates its hepatoprotective role. Fresh juice of tender leaves of *Azadirachta indica* (200 mg/kg body wt. p.o.) inhibited paracetamol (2 g/kg body wt.
15 p.o.)-induced lipid peroxidation and prevented depletion of sulfhydryl groups in liver cells. There was an increase in serum marker enzymes of hepatic damage (aspartate transaminase, alanine transaminase and alkaline phosphatase) after paracetamol administration. *Azadirachta indica* pretreatment stabilized the serum levels of these enzymes. Histopathological observations of liver tissues corroborated these findings
20 (Yanpallewar, 2003). Neem is one of the most widely researched tropical tree, with almost all it's parts being put for a variety of uses. In the present study, the antibacterial effect of Neem mouthwash against salivary levels of streptococcus mutans and lactobacillus has been tested over a period of 2two months. Also it's effect in reversing incipient carious lesions was assessed. While streptococcus mutans
25 ~~was~~were inhibited by Neem mouthwashes, with or without alcohol as well as chlorhexidine, lactobacillus growth was inhibited by chlorhexidine alone. The initial data appears to prove it's effect in inhibiting S. mutans and reversing incipient carious lesions, longer term clinical trials are essential (Vanka et. al. 2001)

Pharmacology: Hepatoprotective activity of *Azadirachta indica* leaf extract against
30 paracetamol induced hepatic damage in rats has already been reported. In the present investigation effects of *Azadirachta indica* leaf extract on blood and liver glutathione, Na(+)/K(+)-ATPase activity and thiobarbituric acid reactive substances against paracetamol induced hepatic damage in rats have been studied with a view to elucidate possible mechanism behind its hepatoprotective action.~~It;~~ it was interesting
35 to observe that *Azadirachta indica* leaf extract has reversal effects on the levels of above mentioned parameters in paracetamol hepatotoxicity (Chattopadhyay 2003). Azadirone-1, a limonoid constituent of *Azadirachta indica* is found to possess

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 potent cytotoxic activity against a panel of human cancer cell lines in our in vitro studies. In vitro screening of a number of semi-synthetic analogues of 1 revealed that the alpha,beta-unsaturated enone moiety or its equivalent conjugated system in A-ring, C-7 acetyloxy/chloroacetyloxy or keto group in B-ring and the furan moiety are responsible for the activity of 1 and its analogues. Compound 1 and two of the semi-
10 synthetic analogues 10 and 13 were found to possess good in vivo antitumor activity in modified hollow fiber animal models (Nanduri, 2003).

***Zanthoxylum armatum* D.C.** Family: Rutaceae

Botanical description: Commonly known as Timur or Nepali Dhaniya, An armed, scandent or erect shrub or a small tree, 6m. tall or more with dense foliage, found in a
15 hot valleys of the Himalaya from Jammu to Bhutan at altitudes of 1,000 - 2,000m. in Khasi hills at 600-1,800m. and in the eastern ghats of in Orissa and Andhra Pradesh at 1,200m. The dried pericarp of ripe fruit of *Zanthoxylum* spp. of family Rutaceae, has been used for epigastric pain accompanied by cold sensation, vomiting, diarrhea and abdominal pain due to intestinal parasitosis, ascariasis and used externally for
20 eczema. The external features as characters of pericarp, the occurrence of hairs on fruit stalk, the presence and location of pigment and crystals of hesperidin, the thickness of the cell walls of endocarp and the presence and shape of nonglandular hairs on fruit stalk were important for the identification of these drugs.

Medicinal uses: The bark, fruits and seeds are extensively used in indigenous system
25 of medicines as a carminative, stomachic and anthelmintic. An extract of fruits is reported to be effective in expelling round worms. Because of their deodorant, disinfectant and ~~anti-septic~~antiseptic properties, the ~~fruit~~fruits are used in dental troubles, and their lotion for scabies.

Phytochemistry: The essential oil obtained from ~~seed~~seeds contains Linalool
30 (64.1%), Linalyl acetate, citral, geraniol methyl cinnamate, limonene, sabinene etc. A new amide designated as armatamide (1)-along with two lignans, asarinin and fargesin, alpha- and beta-amyrins, lupeol, and beta-sitosterol-beta-D-glucoside-has been isolated from the bark of *Zanthoxylum armatum*. The structure of the new compound was deduced by spectral and chemical analysis as N-(4'-methoxyphenyl
35 ethyl)-3, 4-methylenedioxy cinnamoyl amide (Kalia et al, 1999).

Pharmacology: A total of 11 methanol extracts obtained from four different Nepalese *Zanthoxylum* species were screened for their antiproliferative activity against the

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 growth of human keratinocytes (HaCaT cells). The extract obtained from *Z. armatum* barks was highly active with an IC₅₀ value of 11 micrograms/mL. Also, the extracts obtained from *Z. oxyphyllum* barks and roots with IC₅₀ values of 53 and 57 micrograms/mL, respectively, showed potent activity. Their antiproliferative activity was not due to cytotoxic effects on cell membranes, as documented by the activity of
10 lactate dehydrogenase released from the cytoplasm of keratinocytes, which did not exceed that of the control value. Rather, they also protected against radical-induced damage to model membranes stimulated with 2,2'-azo-bis(2-amidinopropane) dihydrochloride (Kumar & Muller, 1999).

15 **OBJECTIVE OF INVENTION**

The objective of the present invention is to provide a synergistic herbal oro-dental care composition useful for various dental problems.

Another objective of the present invention is to provide a composition for
20 treating teeth, for the removal of plaque and caries, and for the prevention of the build-up of calculus.

Yet another objective of the present invention is to provide a novel composition useful in cleansing and brightening teeth and in the treating of plaque and gingivitis without any adverse side effects.

25 Another objective of the present invention is to provide dental compositions, which would cause little or no ecological imbalance of the oral flora.

Further objective of the present invention is to provide a composition comprising a combination of *Citrus karna*, *Zanthoxylum armatum* DC and *Azadirachta indica* and conventional toothpaste ingredients, wherein this composition possesses improved
30 anti-plaque, anti-gingivitis, and cleansing activity.

Another objective of the present invention is to provide a method for treating teeth, which removes plaque and caries, without damaging the teeth.

Yet another objective of the present invention is to provide a method of treating teeth by dissolving away or dispersing plaque and caries, thus essentially eliminating the
35 need for mechanical removal.

SUMMARY

The present invention provides a synergistic herbal oro-dental care composition comprising *Citrus karna*, *Zanthoxylum armatum*, *Azadirachta indica* and *Oriza sativa*

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 and optionally one or more additives which not only provides beneficiary effects of the individual ingredients, but is also highly effective in various dental problems.

The present synergistic herbal oro-dental care composition comprising 20-30% by weight of powdered parts or extract of *Citrus karna*, 20-30 % by weight of powdered parts or extract of *Zanthoxylum armatum*, 20-30% by weight of powdered parts or
 10 extract of *Azadirachta indica*, 20-30% by weight of powdered parts or extract of *Oriza sativa* and optionally one or more additives.

BRIEF DESCRIPTION OF TABLES:

15 TABLE 1 Shows selection of volunteers of age as described below.

TABLE 2 ~~Compare~~Compares the taste of different compositions.

TABLE 3 ~~Compare~~Compares the odor of different compositions.

TABLE 4 ~~Compare~~Compares the texture of different compositions.

TABLE 5 Shows effect of the composition (F1) with and without citrus karna on
 20 dental problems and its effect

TABLE 6 Shows effect of the composition (F4) on dental problems and its effect.

DETAILED DESCRIPTION OF INVENTION

Accordingly the present invention relates to a synergistic herbal Oro-dental
 25 care composition comprising 20-30% by weight of powdered parts or extract of *Citrus karna*, 20-30 % by weight of powdered parts or extract of *Zanthoxylum armatum*, 20-30% by weight of powdered parts or extract of *Azadirachta indica*, 20-30% by weight of powdered parts or extract of *Oriza sativa* and optionally one or more additives.

In an embodiment of the present invention, a synergistic herbal oro-dental care
 30 composition for the treatment of halitosis & mouth ~~Uleer~~Ulcers comprising the pastes or powders of charred husk of ~~Oryza~~Oriza *Oriza sativa*, *Citrus karna*, *Azadirachta indica*, *Zanthoxylum armatum* and *Mint* 20-30%, 20-30%, 20-30%, 20-30%, and 0.5-5%, respectively.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 In another embodiment of the present invention, the dental care composition is used in the form of powder, paste, gel, dental pack, dental floss, mouthwash and chewing gum.

In yet another embodiment of the present invention, the dental care composition is tooth powder.

10 In yet another embodiment of the present invention, wherein *Citrus karna* used is in powder form or as an extract and is obtained from *citrus karna* fruit peal or leaf or flowers.

In still another embodiment of the present invention, wherein the *Zanthoxylum armatum* is used in powder form or extract and is obtained from flowers, leaves roots
15 or fruits of *Zanthoxylum armatum*.

In yet another embodiment of the present invention, wherein *Azadirachta indica* used is in powder form or as an alcoholic extract and is obtained from twigs, bark, seeds or leaves of *Azadirachta indica*.

In yet another embodiment of the present invention, wherein *Oriza sativa* used
20 is in the form of ~~Carbon Black charred~~carbon black charred husk.

In a further embodiment of the present invention, wherein the additives added are selected from the group consisting aromatizing agent, flavoring agent, sweeteners, colorants, polishing material, organic acid, alcohol, essential oils, exert carminative, antiseptic and analgesic agent.

25 In still further embodiment of the present invention, wherein alcohol used is ethanol.

In still another embodiment of the present invention, wherein aromatizing agent used is mint.

In yet embodiment of the present invention, wherein mint used are peppermint or
30 pericarpmint.

In yet another embodiment of the present invention, wherein polishing material is abrasive particulate, having particle size up to 20 microns.

In yet another embodiment of the present invention, wherein organic acid used is acetic acid.

35 In yet another embodiment of the present invention, wherein flavoring ~~agent~~agents used are natural or artificials cinnamon-clove beads.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 In yet another embodiment of the present invention, wherein flavoring ~~agent~~agents used are selected from cinnamon-clove beads, citrus flavor, such as orange and lemon and vanilla.

In still yet another embodiment of the present invention, wherein said composition is useful in treating discolored teeth, ~~tonge, sornesstongue, soreness~~ of oral mucosa, stomatitis, ulcers, traumatic lesions of the mucus, chronic, recurrent cankers, plaque, halitos, gingivitis, dental extraction caries in teeth, gum, stomatitis, calculi, tartar formation, cankers, in protecting oral mucus against lipid peroxidation due to formation of free radicals and against contaminants (ozone, cigarette, smoke) and for soothing, curative, anti-inflammatory effect on epithelial lesions and reducing pain
15 produced by putting false teeth in place.

Further embodiment of the present invention is a synergistic herbal oro-dental care composition, said process comprising the step of mixing 20-30% by weight of powdered parts or extract of *Citrus karna*, 20-30 % by weight of powdered parts or extract of *Zanthoxylum armatum*, 20-30% by weight of powdered parts or extract of
20 *Azadirachta indica*, 20-30% by weight of powdered parts or extract of *Oriza sativa* and optionally one or more additives.

In yet another embodiment of the present invention, powder form of the *citrus karna*, *Zanthoxylum armatum*, *Azadirachta indica* and *Oriza sativa* are obtained by drying leaves or rhizome or aerial parts of plants and grinding them in powder form

- 25 Yet another embodiment of the present invention, *Citrus karna* used is in powder form and is obtained from citrus karna peel off.

Yet another embodiment of the present invention, wherein the *Zanthoxylum armatum* is used in powder form and is obtained from flowers, leaves, roots or fruits of *Zanthoxylum armatum*.

- 30 Yet another embodiment of the present invention, wherein *Azadirachta indica* used is in powder form and obtained from twigs, bark or leaves of *Azadirachta indica*.

Yet another embodiment of the present invention, wherein *Oriza sativa* used is in the form of Carbon Black charred husk.

- Still another embodiment of the present invention, wherein extracts of *citrus karna*, or
35 *Zanthoxylum armatum* or *Azadirachta indica* or *Oriza sativa* are obtained by extracting powder parts of the same with the aqueous alcohol for 4 to 10 days under reduced pressure and at a temperature in the range of 40 to 60 °C.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 Yet another embodiment of the present invention, the ratio between the powdered plants ~~&and~~ the aqueous alcohols is in the range of 1:8 to 1:15.
- Yet another embodiment of the present invention, wherein the additives added are selected from the group comprising aromatizing agent, flavoring ~~agent~~agents, sweeteners, colorants, polishing material and organic acid.
- 10 Still another embodiment of the present invention, wherein aromatizing agent used is mint.
- Yet another embodiment of the present invention, wherein mint used are peppermint or pericarpmint.
- Yet another embodiment of the present invention, wherein polishing material is
- 15 abrasive particulate, having particle size up to 20 microns.
- Yet another embodiment of the present invention, wherein organic acid used is acetic acid.
- Yet another embodiment of the present invention, wherein flavoring ~~agent~~agents used are natural or artificial cinnamon-clove beads.
- 20 Yet another embodiment of the present invention, wherein flavoring agent used are selected form cinnamon-clove beads, citrus flavor such as orange and lemon and vanilla.
- A further embodiment of the present invention relates to use of oro-dental care composition comprising 20-30% by weight of powdered parts or extract of *Citrus*
- 25 *karna*, 20-30 % by weight of powdered parts or extract of *Zanthoxylum armatum*, 20-30% by weight of powdered parts or extract of *Azadirachta indica*, 20-30% by weight of powdered parts or extract of *Oriza sativa* and optionally one or more additives for treating discolored teeth, ~~tonge, sornes~~tongue, soreness of oral mucosa, stomatitis, ulcers, traumatic lesions of the mucus, chronic, recurrent cankers, plaque, ~~halitos,~~
- 30 ~~gingivities~~halitosis, gingivitis, dental extraction caries in teeth, gum, stomatitis, calculi, ~~turtar~~tartar formation, cankers, in protecting oral mucus against lipid peroxidation due to formation of free radicals and against contaminates (ozone, cigarette, smoke) and for soothing, curative, anti-inflammatory effect on epithelial lesions and reducing pain produced by putting false teeth in place.
- 35 A further embodiment of the present invention relates to use of oro-dental care wherein, composition comprising 20-30% by weight of powdered parts or extract of *Citrus karna*, 20-30 % by weight of powdered parts or extract of *Zanthoxylum*

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 *armatum*, 20-30% by weight of powdered parts or extract of *Azadirachta indica*, 20-30% by weight of powdered parts or extract of *Oriza sativa* and optionally one or more additives for treating discolored teeth, tongue, soreness of oral mucosa, stomatitis, ulcers, traumatic lesions of the mucus, chronic, recurrent cankers, plaque, halitos, gingivitis, dental extraction caries in teeth, gum, stomatitis, calculi, tartar formation, 10 cankers, in protecting oral mucus against lipid peroxidation due to formation of free radicals and against contaminants (ozone, cigarette, smoke) and for soothing, curative, anti-inflammatory effect on epithelial lesions and reducing pain produced by putting false teeth in place.

In yet another embodiment of the present invention relates to use of oro-dental care 15 wherein said composition is used in the form of ~~powder, paste, gel, dental floss,~~ mouthwash and chewing gum.

Yet another embodiment of the present invention relates to use of oro-dental care wherein said composition is used as tooth powder.

Yet another embodiment of the present invention relates to use of oro-dental care, 20 wherein the *Citrus karna* is used in powder form or as an extract and as obtained from citrus karna fruit peel or leaf or flowers.

Yet another embodiment of the present invention relates to use of oro-dental care, wherein the *Zanthoxylum armatum* is used in powder form or as an extract and is obtained from flowers, leaves, roots or fruits of *Zanthoxylum armatum*.

25 Yet another embodiment of the present invention relates to use of oro-dental care, wherein *Azadirachta indica* used is in powder form or as an extract and as obtained from twigs, bark, seeds or leaves of *Azadirachta indica*.

Yet another embodiment of the present invention relates to use of oro-dental care, wherein *Oriza sativa* used is in the form of Carbon Black charred husk.

30 Still another embodiment of the present invention relates to use of oro-dental care, wherein the additives added are selected from the group consisting aromatizing agent, flavoring agent, sweeteners, colorants, polishing material, organic acid, alcohol, essential oils, exert carminative, antiseptic and analgesic agent.

Yet another embodiment of the present invention, relates to use of oro-dental care, 35 wherein alcohol used is ethanol.

Yet another embodiment of the present invention relates to use of oro-dental care, wherein aromatizing agent used is mint.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 Yet another embodiment of the present invention relates to use of oro-dental care, wherein mint used are peppermint or pericarpmint.

Yet another embodiment of the present invention relates to use of oro-dental care, wherein polishing material is abrasive particulate, having particle size up to 20 microns.

10 Yet another embodiment of the present invention relates to use of oro-dental care, wherein organic acid used is acetic acid.

Yet another embodiment of the present invention relates to use of oro-dental care, wherein flavoring agent used are natural or artificials cinnamon-clove beads.

15 Yet another embodiment of the present invention relates to use of oro-dental care, wherein flavoring agent used are selected ~~form~~from cinnamon-clove beads, citrus flavor such as orange~~and~~, lemon and vanilla.

The dental product of the present invention is a tooth gel/dentifrice that cleans and brightens/whitens teeth. However, the instant dental product can also be a mouthwash, a paste, a gel, a dental pack, or dental floss. It may also be used to treat gum disease.

20 It is equally well suited to prevent caries, calculi and tartar formation, as well as to help remove them. In order to maintain the preferred pH range in some occasions, it can be desirable to add a buffer system to the dental composition. The selection of the buffer is well known in the art and the buffer is preferably compatible with the other ingredients, that is, it should not have any negative effect on it, and should be non-
25 toxic.

The present invention successfully cleans and brightens teeth while inhibiting and reducing the growth of plaque bacteria, which is achieved when acetic acid or other equivalent organic acid is utilized in combination with conventional dental ingredients in effective concentrations to treat the oral cavity. Small quantities of this
30 unexpectedly simple and nevertheless active component are required to obtain effective inhibition of plaque and other bacteria. Since low quantities of active component can be used in the compositions of this invention, the side effects associated with use of the present invention is correspondingly reduced or eliminated.

The compositions of this invention may be substantially solid or pasty in character
35 such as dental cream, toothpaste, toothpowder or chewing gum. Such solid or pasty oral compositions may also contain polishing materials. Typical polishing materials are abrasive particulate materials having particle sizes of up to about 20 microns.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 The compositions of the present invention may additionally contain sweeteners,
~~flavorant~~flavorants and colorants. Suitable flavorings include both natural and
artificial flavors, and mints such as peppermint, citrus flavors such as orange and
lemon, artificial vanilla, cinnamon, various fruit flavors and the like. In one
embodiment the flavoring agent comprises cinnamon-clove beads. The present
10 invention also involves a method for treating teeth or gums to reduce plaque or
gingivitis comprising applying to the surface of the teeth and/or gums the
compositions of this invention as described above. The compositions can be applied
to the teeth and gums by any conventional means such as brushing, spraying, painting
or rinsing of the oral cavity and the like. The compositions not only cleans and
15 brightens the teeth and retards plaque accumulation, but has been demonstrated to
remove pre-existing plaque as well. Additionally, the compositions show a prolonged
effect on plaque accumulation following cessation of treatment for at least about one
week after use. The following examples are presented to further illustrate this
invention. The examples are intended in an illustrative sense and not in a limitative
20 sense. The present invention includes the embodiments described and shown and any
equivalents thereof. All parts and percentages are on a weight basis unless otherwise
indicated.

The dental product of the present invention is highly acceptable to consumers of all
age group in respect of its taste, odor and texture. The present dental compositions are
25 capable to prevent various dental problems. Although all the ingredients of the present
invention are known to posses beneficial properties against dental problems, it should
not be assumed that the product of the present invention is an obvious combination of
the individual ingredients.

The use of any product does not only depend upon the bioactivity of the product, but
30 also on the acceptance of the product. Products which do not have good flavor, odor,
feel and other organoleptic properties have not been found as successful. Although
each of the individual ingredient is ~~known~~known to posses beneficial bioactivity
properties, their flavor, odor have not been found acceptable to people, for example
Azadirachta indica has a very bitter taste due to which chewing. Its bark is very
35 displeasing. Thus, in the present invention application the inventor ~~have~~has aimed for
preparing a composition which, not only, provides the beneficiary effects of all
ingredients, but ~~are~~is also capable to the users. The acceptance of the synergistic

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 composition of the present invention has been tested using ~~of~~ various age groups. Also, the synergistic composition of the present invention ~~of the present invention is~~ hereafter referred to as F1. Four other compositions F2 to F5 have been prepared ~~&and~~ compared with F1 to prove its synergistic effect.

In the following examples the process for preparing the synergistic compositions F2
 10 to F5 are described.

The ~~applicant~~applicants have also conducted test on 100 volunteers to establish the synergistic nature of the composition F1.

Example 1 # Composition (F1)

20 % wt	Carbon black from Husk of Oryza <u>Oriza</u> Sativa
15 30% wt	<i>Citrus karna</i>
25% wt	<i>Azadirachta indica</i>
20% wt	<i>Zathoxylum armatum</i>
Rest	Mint

~~Oryza~~Oriza Sativa, *Citrus karna*, *Azadirachta indica*, and *Zathoxylum armatum*
 20 were collected and dried in shade. The dried material (1Kg) is then powdered and extracted with 50 % aqueous alcohol (3 L) for 5 days. At the end of this, the solvent is decanted and filtered if necessary to remove the plant debris. The extract is then concentrated under vacuum at less than ~~50~~⁰50°C. Then the extract is lyophilised to obtain the extract in powder form .15 g of starch is mixed with water
 25 and heated to form a paste.

The formulation is useful for the treatment of various dental problems.

Example 2 # Composition (F2)

25% wt.	Carbon black from Husk <u>husk</u> of Oryza <u>Oriza</u> Sativa
20% wt.	<i>Azadirachta indica</i>
30 20% wt.	<i>Zathoxylum armatum</i>
Rest	Mint

~~Oryza~~Oriza Sativa, *Azadirachta indica*, and *Zathoxylum armatum* were collected and dried in shade. The dried material (1Kg) is then powdered and extracted with 50 % aqueous alcohol (3 L) for 5 days. At the end of this, the solvent is decanted and
 35 filtered if necessary to remove the plant debris. The extract is then concentrated under vacuum at less than 50 °C. Then the extract is lyophilised to obtain the extract in powder form.15 g of starch is mixed with water and heated to form a paste.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 The formulation is useful for the treatment of various dental problems.

Example 3 # Composition (F3)

- | | |
|---------|---|
| 25% wt. | Carbon black from Husk of Oryza <u>Oriza</u> <i>Sativa</i> |
| 30% wt. | <i>Citrus karna</i> |
| 20% wt. | <i>Zathoxylum armatum</i> |
| 10 Rest | Mint |

- ~~Oryza~~Oriza *Sativa*, *Citrus karna* and *Zathoxylum armatum* were collected and dried in shade. The dried material (1Kg) is then powdered and extracted with 50 % aqueous alcohol (3 L) for 5 days. At the end of this, the solvent is decanted and filtered if necessary to remove the plant debris. The extract is then concentrated under vacuum at less than 50 °C. Then the extract is lyophilised to obtain the extract in powder form. 15 g of starch is mixed with water and heated to form a paste.

The formulation is useful for the treatment of various dental problems.

Example 4 # Composition (F4)

- | | |
|-----------|---|
| 20 20% wt | Carbon black from Husk of Oryza <u>Oriza</u> <i>Sativa</i> |
| 30% wt | <i>Citrus karna</i> |
| 25% wt | <i>Azadirachta indica</i> |
| Rest | Mint |

- ~~Oryza~~Oriza *Sativa*, *Citrus karna* and *Azadirachta indica* were collected and dried in shade. The dried material (1Kg) is then powdered and extracted with 50 % aqueous alcohol (3 L) for 5 days. At the end of this, the solvent is decanted and filtered if necessary to remove the plant debris. The extract is then concentrated under vacuum at less than 50 °C. Then the extract is lyophilised to obtain the extract in powder form. 15 g of starch is mixed with water and heated to form a paste.

- 30 The formulation is useful for the treatment of various dental problems.

Example 5 # Composition (F5)

- | | |
|---------|---------------------------|
| 30% wt | <i>Citrus karna</i> |
| 25% wt | <i>Azadirachta indica</i> |
| 20% wt | <i>Zathoxylum armatum</i> |
| 35 Rest | Mint |

Citrus karna, *Azadirachta indica*, and *Zathoxylum armatum* were collected and dried in shade. The dried material (1Kg) is then powdered and extracted with 50 % aqueous

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 alcohol (3 L) for 5 days. At the end of this, the solvent is decanted and filtered if necessary to remove the plant debris. The extract is then concentrated under vacuum at less than ~~50~~⁵⁰°C. Then the extract is lyophilised to obtain the extract in powder form. 15 g of starch is mixed with water and heated to form a paste.

Example 6 # Testing of various dental compositions F1 to F5.

- 10 The compositions are useful for the treatment of various dental problems. Samples of above composition (s) were given to volunteers on a prescribed performa during August 2002 to August 2003. Response was satisfactory. Sample size: 100 human beings/sample

Area covered: India (State: Uttar Pradesh, City: Lucknow)--95% and outside the
15 **city Lucknow--5%**

Methodology: Direct conversation with volunteers and questionnaire method.

TABLE 1: Selection of volunteers of age as described below.

Years				F1			F2			F3			F4			F5		
Age	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total	M	F	Total
<20	4	4	8	5	5	10	5	4	9	5	8	13	10	7	17			
20 – 40	32	23	55	31	22	53	34	20	54	35	26	61	8	35	43			
> 40	31	6	37	30	7	37	33	4	37	16	10	26	17	23	40			
Total	67	33	100	66	34	100	72	28	100	56	44	100	35	65	100			

The data represents the selection of male and female volunteers approached themselves or volunteers recommended or forwarded the formulation(s) to their
20 colleagues.

TABLE 2: Compares the taste of different composition (s).

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

Age	F1		F2		F3		F4		F5	
Years	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement	Good/ accepted	Needs Improvement
<20	06	02	04	06	04	05	06	07	12	05
20 – 40	51	04	28	25	20	34	30	31	05	38
> 40	35	02	25	12	30	07	06	20	20	20
Total	92	08	57	43	54	46	42	58	37	63

- 5 On the basis of the above result, it clearly shows that formulation F1 is highly acceptable compare to other formulations from the taste point of view and showed 92% good and accepted.

TABLE 3: Compares the odor of different composition(s).

Age	F1		F2		F3		F4		F5	
Years	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement	good/ accepted	Needs Improvement
<20	05	03	03	07	03	06	10	03	11	06
20 – 40	54	01	33	20	24	30	40	21	07	36
> 40	30	07	29	08	25	12	18	08	25	15
Total	89	11	65	35	52	48	68	32	43	57

- 10 On the basis of the above result it clearly shows that formulation F1 (89%) is acceptable compare to other formulations from the odour point of view.

TABLE 4: Compares the texture of different composition (s).

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

Age	F1		F2		F3		F4		F5	
Years	good/ accepte d	Needs Improv ement	good/ accepte d	Needs Improv ement	good/ accepte d	Needs Improv ement	good/ accepte d	Needs Improv ement	Good/ accepte d	Needs Improv ement
<20	06	02	02	08	02	07	06	07	09	08
20 – 40	53	02	23	30	21	33	34	27	14	29
> 40	32	05	31	06	12	25	20	06	21	19
Total	91	09	56	44	35	65	60	40	44	56

5

On the basis of the above result it clearly shows that formulation F1 (91%) is acceptable compare to other formulations from the texture point of view.

10

15

TABLE 5: Effect of the composition (F1) with and without citrus karna on dental Problemsproblems and its effect:

S.No.	Problems*	Highly effective (%)		Moderately effective (%)		Low/slow effective (%)		No action/(%)		Total Persons used (%)
		With	With-out	With	With-out	With	With-out	With	With-out	
1.	Bleeding gums	54	40	12	8	32	42	02	10	100
2.	Swollen gums	48	42	26	23	23	30	3	5	100
3.	Toothache	18	18	28	28	42	45	12	9	100
4.	Yellowing/staining of teeth	35	30	26	22	29	40	10	8	100
5.	Loosening of teeth	8	8	--		79	79	11	11	100
6.	Foul odour of mouth	26	20	29	22	45	50	--	8	100
7.	Sensitivity to cold hot water/Food	20	18	11	10	58	65	11	6	100

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 On the basis of the above result it clear that the formulation F1 is acceptable and highly effective and recommended, from this it is clear that the potency is increased.

TABLE 6: Effect of the composition (F4) on Problems and its effect:

S.No	Problems*	Highly effective (%)	Moderately effective (%)	Low/slow effective (%)	No action/(%)	Total Personsused (%)
1.	Bleeding gums	45	11	36	08	100
2.	Swollen gums	38	30	29	03	100
3.	Toothache	22	26	44	08	100
4.	Yellowing/stainin g of teeth	31	30	19	20	100
5.	Loosening of teeth	8	05	68	19	100
6.	Foul odour of mouth	21	32	47	--	100
7.	Sensitivity to cold hot water/Food	15	14	61	10	100

10

On the basis of the above results it clearly shows that formulation F4 can also be acceptable but it is not so effective as compare to F1 formulation containing ~~Oryza~~Oriza *Sativa*, *Citrus karna*, *Azadirachta indica* and *Zathoxylum armatum*. It was found that this composition F1 is highly acceptable to consumers and acceptable up to 92 % people, 54 % to 89 % people found F1 composition is highly effective in bleeding gums, 48 % to 76 % people found the same composition is highly useful in swollen gums, 26 to 76 % people found beneficial in odor of mouth, 8% to 35 % people found it effective in loosening of teeth. On the basis of the above results indicates that the composition F1 is a acceptable, highly effective and recommended for use. The product is advised to be used with brush or finger either in the morning or ~~nighttime~~night time or when ~~falls-discomfort~~ is felt in the mouth and as used as mouth freshener.

15

20

The F2 composition contains powdered parts or extract of the three plant i.e ~~Oryza~~Oriza *Sativa*, *Azadirachta indica* and *Zathoxylum* ~~armatum~~armatums. It was found that the acceptable level for this composition is only up to 57 % people. F3 composition contains powdered parts or extract of the four plant i.e ~~Oryza~~Oriza *Sativa*, *Citrus karna* and *Zathoxylum armatum*. It was found that the acceptable level for the same is only up to 54 % people. F4 composition contains powdered parts or extract of three plants i.e. ~~Oryza~~, Oriza *Sativa*, *Citrus karna*, and *Azadirachta indica* which is acceptable but not so effective in comparison to formulation F1.

25

30

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 Composition F5 contains powdered ~~plant~~plants or extracts of three plants i.e. *Citrus karna*, *Azadirachta indica* and *Zathoxylum armatum*, which have very low acceptance level and effective to consumers.

The composition of the present invention can be delivered in common dental products, such as tooth pastes or dentifrices, tooth powders, mouthwashes, dental
10 floss, toothpicks, chewing gum and the like. The dental product of the present invention cleans, and brightens/ and whitens teeth. It is also suitable for the treatment of gum disease. It is equally well suited for the prevention of caries, calculi and tartar formation as well as to help remove them. The composition of the present invention need not to be in semi-solid or solid form, i.e., paste or powder, but can be equally
15 used as a solution to be brought adequately into contact with the teeth for a sufficient period of time to enable the plaque and caries to be dissolved and the teeth to be cleansed and brightened, e.g., as a conventional mouth rinse or mouth wash. The present invention also includes a method of treating teeth in dentistry, for the prevention of calculus, and/or the removal of caries, and/or the dissolving of plaque, and/or brightening/whitening teeth, comprising bringing into contact with the teeth a
20 composition comprising acetic acid and preferably, a preparation containing conventional tooth paste or dentifrice ingredients. Conventional ingredients include, but are not limited to colorants, abrasives and polishing agents, flavoring agents, sweeteners, buffers, diluents, surfactants, gum, sodium fluoride, glycerol, chelating
25 agents, and other ingredients well-known as dental additives and carriers. The preferred dental product of the present invention contains *Citrus karna* preferably, the composition also contains *Neem*. In accordance with the scope of this invention, it is desirable to add a buffer system to the dental composition. Such a buffer is preferably compatible with the preferred compounds, that is, it should not have any negative
30 effect on same, and should be non-toxic i.e. 'Carbon black' obtained from the Charred husk of ~~Oryza~~Oriza *sativa*.

ADVANTAGE OF PRESENT INVENTION

- 35 1. Since the components used in the formulation is of herbal origin ~~so~~the product is safe to be used orally, as they have no or nil adverse or side effects on the gums and teeth.
2. The product is economically viable and eco-friendly.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

- 5 3. It doesn't contain tobacco or any other carcinogenic habit forming substance as ~~ingredient~~ingredients to ~~spoil~~spoil the teeth and gums.

Substitute Specification
VERSION WITH MARKINGS TO SHOW CHANGES

5 **HERBAL ORO-DENTAL CARE COMPOSITION AND PROCESS FOR
 PREPARING THE SAME**

10

ABSTRACT

This invention relates to novel dental compositions and methods for preventing dental plaque and caries formation and generally for inhibiting tooth decay and brightening
15 /whitening teeth/~~mouth-ulcer~~. The compositions of this invention comprise herbs such as *Citrus karna* raf., *Zanthoxylum armatum* D.C. and *Azadirachta indica* A. Juss. ~~there-of~~thereof which can be combined with pharmaceutically acceptable carriers or diluents to be administered in the form of conventional dental compositions. The compositions of the present invention, also preferably, contain *Mint*.

20